MAY 1 5 2013

5.0 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K123930

1. **Submitter name, address, contact**

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
(585) 453-3143
Contact Person: Michael Byrne

2. **Preparation Date**

December 19, 2012

3. **Device name**

Trade or Proprietary Names:
VITROS® Chemistry Products HCY 2 Reagent
VITROS® Chemistry Products HCY 2 Performance Verifiers I, II & III

Common Names:
HCY assay and controls

Classification Names:
Urinary homocystine (nonquantitative) test system (21 CFR 862.1377)
Class II

Quality Control material (assayed and unassayed) (21 CFR 862.1660)
Class I (reserved). Since these devices (VITROS® HCY 2 Performance Verifiers I, II & III) are assayed controls, they meet the reserved criteria under Section 510(l) of the Food, Drug, and Cosmetic Act.

Product Code:
LPS, JJX

Panel:
Clinical Chemistry

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4. Predicate Devices

The VITROS® Chemistry Products HCY 2 assay is substantially equivalent to the previously cleared VITROS® Chemistry Products HCY Reagent (K061588).

The VITROS® Chemistry Products HCY 2 Performance Verifiers are substantially equivalent to the previously cleared VITROS® Chemistry Products HCY Performance Verifiers (K061588).

5. Device description

The VITROS® Chemistry Products HCY 2 Reagent is used in conjunction with the VITROS® Chemistry Products Calibrator Kit 27 and VITROS® Chemistry Products FS Diluent Pack 2 (BSA/Saline) on VITROS® 5,1 FS Chemistry Systems, VITROS® 4600 Chemistry Systems, and the VITROS® 5600 Integrated Systems to quantitatively measure total homocysteine concentration in human serum and plasma.

The VITROS® Chemistry Products HCY 2 Reagent consists of one dual chambered reagent pack containing two ready-to-use liquid reagents, one in each chamber. Disulfide linked homocysteine (oxidized forms) in the sample is reduced by Tris (2-Carboxyethyl) Phosphine hydrochloride (TCEP) to form reduced homocysteine. Reduced homocysteine reacts with serine in the presence of cystathionine β-synthase (CBS) to form L-cystathionine. L-cystathionine is broken down by cystathionine β-lyase (CBL) to produce homocysteine, pyruvate and ammonia. Pyruvate is reduced to lactate by lactate dehydrogenase (LDH) using NADH as coenzyme. The concentration of homocysteine is directly proportional to the amount of NADH converted to NAD^+ and is measured spectrophotometrically at 340 nm.

The VITROS® Chemistry Products Calibrator Kit 27 is prepared from an aqueous solution containing amino acids and inorganic acid. These standards are used to calibrate the VITROS® 5,1 FS Chemistry Systems, VITROS® 4600 Chemistry Systems, and VITROS® 5600 Integrated Systems for the quantitative measurement of homocysteine.

The VITROS® Chemistry Products HCY 2 Performance Verifiers I, II and III are prepared from processed human serum to which amino acid and preservative have been added. These are assayed controls used to monitor performance of VITROS® Chemistry Products HCY and VITROS® Chemistry Products HCY 2 Reagents on VITROS® Systems.

The VITROS® Chemistry Products FS Diluent Pack 2 (Saline/BSA) is a common reagent that is used by multiple assays on VITROS® Systems. This is a dual chambered package containing two ready-to-use liquid diluents. Diluent 1 is prepared from processed water to which inorganic salt has been added. Diluent 2 is prepared from processed water to which bovine serum albumin, inorganic salts and preservatives have been added.

6. **Device intended uses**

VITROS® Chemistry Products HCY 2 Reagent: For *in vitro* diagnostic use only. VITROS® Chemistry Products HCY 2 Reagent is used on VITROS® Systems to quantitatively measure total homocysteine concentration in human serum and plasma. Serum and plasma homocysteine levels can assist in the diagnosis and treatment of patients suspected of having hyperhomocysteinemia and homocystinuria.

VITROS® Chemistry Products HCY 2 Performance Verifiers I, II & III: For *in vitro* diagnostic use only. VITROS® Chemistry Products HCY 2 Performance Verifiers are assayed controls used to monitor performance of VITROS® Chemistry Products HCY and VITROS® Chemistry Products HCY® 2 Reagents on VITROS® Systems.

7. **Comparison to predicate devices:**

VITROS® Chemistry Products HCY 2 Reagent is substantially equivalent to the VITROS® Chemistry Products HCY Reagent (K061588) (predicate device) which was cleared by the FDA for IVD use.

A least squares linear regression analysis using an n=110, demonstrated the following relationship: y = 1.00 x + 0.42 (µmol/L) with a correlation coefficient (r) of 0.997 where y = results obtained using the VITROS® Chemistry Products HCY 2 assay and x = results obtained with the commercially available VITROS® Chemistry Products HCY Assay in conventional/SI units (µmol/L) on the VITROS 5,1 FS Chemistry System.

A least squares linear regression analysis using an n=123, demonstrated the following relationship: y = 0.98 x + 0.60 (µmol/L) with a correlation coefficient (r) of 0.997 where y = results obtained using the VITROS® Chemistry Products HCY 2 assay on the VITROS® 4600 Chemistry System and x = results obtained with the commercially available VITROS® Chemistry Products HCY Assay in conventional/SI units (µmol/L) on the VITROS 5,1 FS Chemistry System.

A least squares linear regression analysis using an n=111, demonstrated the following relationship: y = 0.99 x + 0.46 (µmol/L) with a correlation coefficient (r) of 0.993 where y = results obtained using the VITROS® Chemistry Products HCY 2 assay on the VITROS® 5600 Integrated System and x = results obtained with the commercially available VITROS® Chemistry Products HCY Assay in conventional/SI units (µmol/L) on the VITROS 5,1 FS Chemistry System.

The VITROS® Chemistry Products HCY 2 Performance Verifiers I, II & III are substantially equivalent to the VITROS® Chemistry Products HCY Performance Verifiers I, II & III (K061588) (predicate device) which was cleared by the FDA for IVD use.

In addition to correlation studies, bench testing was performed to determine assay precision, linearity, specificity, expected values, limit of detection, dilution and specimen matrix of the VITROS® Chemistry Products HCY 2 assay.

Table 1 Similarities and differences of the assays performed using the VITROS® Chemistry Products HCY 2 Reagent and the VITROS® Chemistry Products HCY Reagent.

Device Characteristic	VITROS® HCY 2 Reagent (New device)	VITROS® HCY Reagent (Predicate device)
Intended Use	For *in vitro* diagnostic use only. VITROS Chemistry Products HCY 2 Reagent is used on VITROS® Systems to quantitatively measure total homocysteine concentration in human serum and plasma. Serum and plasma homocysteine levels can assist in the diagnosis and treatment of patients suspected of having hyperhomocysteinemia and homocystinuria.	Same, but specific to VITROS Chemistry Products HCY Reagent
Reagent Packs	One dual chamber reagent pack containing one reagent in each chamber	Two dual chamber reagent packs containing three reagents, one reagent in each of three chambers
Tests per pack/set	50 tests/reagent pack/ 6 reagent packs/carton=300 tests/carton	50 tests/ 2 reagent packs/ 6 reagent packs/carton=150 tests/carton
Reactive ingredients	Lactate Dehydrogenase (LDH)= 37.9 KU/L Serine=0.8 mmol/L (0.08% w/v) Nicotinamide Adenine Dinucleotide (NADH)=0.5 mmol/L (0.03% w/v) Tris (2-Carboxyethyl) phosphine hydrochloride (TCEP)=2.9 mmol/L (0.08% w/v) Cystathionine β-lyase=16.4 KU/L Cystathionine β-synthase=0.748 KU/L	Lactate Dehydrogenase (LDH)= 65 KU/L Serine=1.3 mmol/L (0.01% w/v) Nicotinamide Adenine Dinucleotide (NADH)=0.56 mmol/L (0.04% w/v) Tris (2-Carboxyethyl) phosphine hydrochloride (TCEP)=26.3 mmol/L (0.8% w/v) Cystathionine β-lyase=16 KU/L Cystathionine β-synthase=22 KU/L
Analyte measured	Homocysteine	Same
Sample Type	Serum and plasma	Same
Measurement Type	Quantitative	Same
Reportable Range	2.0 –50.0 µmol/L	1.0 –50.0 µmol/L

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Device Characteristic	VITROS® HCY 2 Reagent (New device)	VITROS® HCY Reagent (Predicate device)
Sensitivity (LoQ)	1.29 µmol/L	0.96 µmol/L
Calibrator levels	Two levels (0, 28 µmol/L)	Same
Calibrator format	Liquid	Same
Calibrator matrix	Aqueous solution containing amino acids and inorganic acid	Same
Instrumentation	Automated clinical chemistry analyzer	Same
Calibration Traceability Standard	NIST 1955	Same
Reference Interval	Males: 6.6 – 14.8 µmol/L Females: 4.7 – 12.6 µmol/L	Same

Table 2 Similarities and differences of the device characteristics between the VITROS® Chemistry Products HCY 2 Performance Verifiers I, II & III with the predicate device VITROS® Chemistry Products HCY Performance Verifiers I, II & III

Device Characteristic	VITROS® HCY 2 Performance Verifiers (New Device)	VITROS® HCY Performance Verifiers (Predicate Device)
Analytes Reported	Homocysteine in VITROS® HCY and HCY 2 Reagents	Homocysteine in VITROS® HCY Reagent
Vial Volume	1.5 mL/vial	5 mL/vial
Intended Use Statement	For *in-vitro* diagnostic use only. VITROS® Chemistry Products HCY 2 Performance Verifiers are assayed controls used to monitor performance of VITROS® HCY and VITROS® HCY 2 Reagents on VITROS® Systems.	For *in-vitro* diagnostic use only. VITROS® Chemistry Products HCY Performance Verifiers are assayed controls used to monitor performance of VITROS® HCY Reagents on VITROS® System.
Matrix	The Performance Verifiers are prepared from processed human serum with preservatives added.	Same
Product Type	Assayed Control	Same
Format	Liquid	Same
Number of levels	Three	Same
Nominal Values	7.0, 12.5, and 25 µmol/L	7.0, 12, and 46 µmol/L

Conclusions: The data presented in this premarket notification provide a reasonable assurance that the VITROS® Chemistry Products HCY 2 Reagent and the VITROS® Chemistry Products HCY 2 Performance Verifiers are safe and effective for the stated intended uses and are substantially equivalent to the cleared predicate devices. Equivalence to the predicates was demonstrated using a commercially available assay along with patient samples.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 15, 2013

Ortho-Clinical Diagnostics, Inc.
C/O Michael Byrne
100 Indigo Creek Drive
ROCHESTER NY 14626-5101

Re: K123930
Trade/Device Name: VITROS® Chemistry Products HCY 2 Reagent,
VITROS® Chemistry Products HCY 2 Performance Verifiers I, II & III
Regulation Number: 21 CFR 862.1377
Regulation Name: Urinary homocystine (nonquantitative) test system
Regulatory Class: II
Product Code: LPS, JJX
Dated: April 03, 2013
Received: April 04, 2013

Dear Mr. Byrne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k123930

Device Name: VITROS® Chemistry Products HCY 2 Reagent
VITROS® Chemistry Products HCY 2 Performance Verifiers I, II, and III

Indications for Use: For *in vitro* diagnostic use only. VITROS® Chemistry Products HCY 2 Reagent is used on VITROS® Systems to quantitatively measure total homocysteine concentration in human serum and plasma. Serum and plasma homocysteine levels can assist in the diagnosis and treatment of patients suspected of having hyperhomocysteinemia and homocystinuria.

For *in vitro* diagnostic use only. VITROS® Chemistry Products HCY 2 Performance Verifiers are assayed controls used to monitor performance of VITROS® Chemistry Products HCY and VITROS® Chemistry Products HCY 2 Reagents on VITROS® Systems.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Yung W. Chan -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k123930